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INFORMATION DISCLOSURE STATEMENT Applicant(s): Ilanson et al. Confirmation No.: 6198

Filing Date: March 21, 2001 Group: 1655 634

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n	HADEN	4,683,194	07/28/87	Saiki et al.	-			
		4,683,195	07/28/87	Mullis et al.		DEC		
		5,994,066	11/30/99	Bergeron et al.		NLO	I V	inspired the
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w				ance Problem," <u>Clin.</u>				
		1	n types of tra	ymerase chain reactio ansferable β-lactamase 5 (1991).		- .		
	Arlet et al., "Molecular characterization by PCR-restriction fragment length polymorphism of TEM β-lactamases," <u>FEMS Microbiol. Lett.</u> , 134:203-208 (1995).							
	Arlet et al., "Substitution of alanine for aspartate at position 179 in the SHV-6 extended-spectrum β-lactamase," FEMS Microbiol. Lett., 152:163-167 (1997).							
	Barnaud et al., "Cloning and sequencing of the gene encoding the AmpC β-lactamase of Morganella morganii," FEMS Microbiol. Lett. 148:15-20 (1997).							
		Bauernfeind et al., "A New Plasmidic Cefotaximase in a Clinical Isolate of Escherichia coli," <u>Infection</u> , 18(5):294-298 (1990).						
		•		equence of the SHV-S "Antimicrob. Agents	•			

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OMB No. 0651-0011



INFORMATION DISCLOSURE STATEMENT

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1	SIP		<u></u>	
AU	17	2001	C186	Birnboim et al., "A rapid alkaline extraction procedure for screening recombinant plasmid DNA," Nucleic Acids Res., 7(6):1513-1523 (1979).
ENT &	PADE	ARX		Bradford et al., "SHV-7, a Novel Cefotaxime-Hydrolyzing β-Lactamase, Identified in <i>Escherichia coli</i> Isolates from Hospitalized Nursing Home Patients," Antimicrob. Agents Chemother., 39(4):899-905 (1995).
				Bradford et al., "Multiply Resistant Klebsiella pneumoniae Strains from Two LL Chicago Hospitals: Identification of the Extended-Spectrum TEM-12 and TEM-10." Ceftazidime-Hydrolyzing β-Lactamases in a Single Isolate," Antimicrob. Agents Chemother., 38(4): 761-766 (1994).
	,			Bret et al., "Chromosomally Encoded AmpC-Type β-Lactamase in a Clinical Isolate of <i>Proteus mirabilis</i> ," Antimicrob. Agents Chemother., 42(5):1110-1114 (1998).
				Brun-Buisson et al., "Transferable Enzymatic Resistance to Third-Generation Cephalosporins During Nosocomial Outbreak of Multiresistant Klebsiella Pneumoniae," The Lancet, 2:302-306 (1987).
				Burns et al., "An Integrated Nanoliter DNA Analysis Device," Science, 282:484-487 (1998).
				Caniça et al., "Molecular Diversity and Evolution of bla _{tem} Genes Encoding β-Lactamases Resistant to Clavulanic Acid in Clinical E. coli," J. Mol. Evol., 44:57-65 (1997).
				Carter et al., "Use of a non-radioactive hybridisation assay for direct detection of gram-negative bacteria carrying TEM β-lactamase genes in infected urine," J. Med. Microbiol, 28:113-117 (1989).
				Check, "Clinical Microbiology Eyes Nucleic Acid-Based Technologies," <u>ASM News</u> , <u>64</u> (2):84-89 (1998).
				Crea et al., "Chemical synthesis of genes for human insulin," Proc. Natl. Acad. Sci. USA, 75(12):5765-5769 (1978).
				Crosa et al., "Plasmids," Manual of Methods for General Bacteriology, Gerhardt et al., eds., American Society for Microbiology, Washington, DC, Ch.15, pgs. 266-282 (1981).
				Curran et al., "A rapid immunoassay method for the direct detection of PCR products: application to detection of TEM β-lactamase genes," J. Med. Microbiol., 45:76-78 (1996).

EXAMINER Lule cu	Date Considered 3/27/2003
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INFORMATION DISCLOSURE STATEMENT

Atty. Docket No.: 180.00030103 Serial No.: 09/814,252

Applicant(s): Hanson et al. Confirmation No.: 6198

Filing Date: March 21, 2001 Group: 1635

~II	DE N	
AUG 1	7 2001	Galleni et al., "Sequence and comparative analysis of three Enterobacter cloaca ampC β-lactamase genes and their products," <u>Biochem. J., 250, 753-760 (1988).</u>
Y & TR	DEMINITION	Gold et al., "Antimicrobial-Drug Resistance," The New England Journal of Medicine, 335(19):1445-1453 (1996).
		Gonzalez Leiza et al., "Gene sequence and biochemical characterization of FOX-1-from Klebsiella pneumoniae, a new AmpC-type plasmid-mediated beta-lactamase with two molecular variants," Antimicrob. Agents Chemother., 38(9):2150-7 (1994).
		Hanson et al., "Molecular Characterization of a Multiply Resistant <i>Klebsiella</i> pneumoniae," Abstract C-59, <u>37th ICAAC</u> , Toronto, Ontario, Canada, September 28-October 1 (1997).
•		Hanson et al., "A Novel TEM-Type Extended Spectrum Beta-Lactamase Expressed in Three Different Genera of Enterobacteriaceae from South Africa," Abstract C-5, pg 70, 38th ICAAC, San Diego, California, September 24-27 (1998).
		Hanson et al., "Molecular characterization of a multiply resistant <i>Klebsiella</i> pneumoniae encoding ESBLs and a plasmid-mediated AmpC," <u>J. Antimicrob.</u> Chemother., 44:377-380 (1999).
		Hanson et al., "Regulation of Inducible AmpC Beta-Lactamase Expression Among Enterobacteriaceae," <u>Curr. Pharmac. Design</u> , <u>5</u> (11):881-894 (1999).
		Hibbert-Rogers et al., "Convergent evolution of TEM-26, a β-lactamase with extended-spectrum activity," <u>J. Antimicrob. Chemother.</u> , 33:707-720 (1994).
		Huletsky et al., "Nucleotide Sequence and Phylogeny of SHV-2 β-Lactamase," Antimicrob. Agents Chemother., 34(9):1725-1732 (1990).
		Jacoby et al., "More Extended-Spectrum β-Lactamases," <u>Antimicrob. Agents</u> <u>Chemother., 35(9):1697-1704 (1991).</u>
		Jarlier et al., "Extended Broad-Spectrum β-Lactamases Conferring Transferable Resistance to Newer β-Lactam Agents in Enterobacteriaceae: Hospital Prevalence and Susceptibility Patterns," Rev. Infect. Dis., 10(4):867-878 (1988).
		 Jones, "The Emergent Needs for Basic Research, Education, and Surveillance of Antimicrobial Resistance: Problems Facing the Report from the American Society for Microbiology Task Force on Antibiotic Resistance," <u>Diagn. Microbiol. Infect.</u> <u>Disease</u> , <u>25</u> :153-161 (1996).

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INFORMATION DISCLOSURE STATEMENT

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 Serial No.: 09/814,252

 Applicant(s): Hanson et al.
 Confirmation No.: 6198

 Filing Date: March 21, 2001
 Group: 1655
 63 4

OIP AUG 17	ZO11			Jones, "Important and Emerging β-Lactamase-mediated Resistances in Hospital based Pathogens: The Amp C Enzymes," <u>Diagn. Microbiol. Infect. Dis.</u> , 31:461 466 (1998).
TA TRADE	MARK			Leung et al., "Rarity of transferable β-lactamase production by <i>Klebsiella</i> species," <u>J. Antimicrob. Chemother.</u> , <u>39</u> :737-745 (1997).
			. }	M'Zali et al., "Brief reports: Detection of mutations conferring extended- spectrum activity on SHV β-lactamases using polymerase chain reaction single strand conformational polymorphism (PCR-SSCP)," J. Antimicrob. Chemother., 37:797-802 (1996).
				Mabilat et al., "Direct Sequencing of the Amplified Structural Gene and Promoter for the Extended-Broad-Spectrum β-Lactamase TEM-9 (RHH-1) of Klebsiella pneumoniae," <u>Plasmid</u> , 23:27-34 (1990).
				Mabilat et al., "Development of "Oligotyping" for Characterization and Molecular Epidemiology of TEM β-Lactamases in Members of the Family Enterobacteriaceae," Antimicrob. Agents Chemother., 34(11):2210-2216 (1990).
				Maniatis et al., Molecular Cloning: A Laboratory Manual, Cold Spring Harbor, NY (Title page, Publication page, and Table of Contents only) 8 pgs. (1982).
				Marchese et al., "Characterization of FOX-3, an AmpC-Type Plasmid-Mediated β-Lactamase from an Italian Isolate of <i>Klebsiella oxytoca</i> ," <u>Antimicrob. Agents Chemother.</u> , 42(2):464-467 (1998).
		:		Martineau, Species-specific and ubiquitous DNA-based assays for rapid identification of Staphylococcus epidermidis," <u>J Clin Microbiol</u> ., <u>34</u> (12):2888-93 (1996).
				Medeiros, "Recent Increases in Resistance: Mechanisms and Organisms: Evolution and Dissemination of β-Lactamases Accelerated by Generations of β-Lactam Antibiotics," Clin. Inf. Dis., 24(Suppl 1):S19-45 (1997).
				Mercier et al., "Cloning of SHV-2, OHIO-1, and OXA-6 β-Lactamases and Cloning and Sequencing of SHV-1 β-Lactamase," <u>Antimicrob. Agents</u> <u>Chemother.</u> , 34(8):1577-1583 (1990).
	V)		Mugnier et al., "A TEM-Derived Extended-Spectrum β-Lactamase in Pseudomonas aeruginosa," Antimicrob. Agents Chemother., 40(11):2488-2493 (1996).

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INFORMATION DISCLOSURE STATEMENT

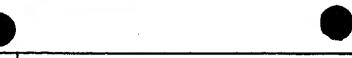
 Atty. Docket No.: 180.00030103
 Serial No.: 09/814,252

 Applicant(s): Hanson et al.
 Confirmation No.: 6198

 Filing Date: March 21, 2001
 Group: 1655 / 63 4

AUG 1 7	Z001	PRIOE SON	<u> </u>	Mullis et al., "Specific Enzymatic Amplification of DNA In Vitro: The Polymerase Chain Reaction," Cold Spring Harbor Symposia on Quantitative Biology, Cold Spring Harbor Laboratory, Cold Spring Harbor, NY, 51:263-273 (1986).
CALL TRAI	DEMARY		}	Mullis et al., "Specific Enzymatic Amplification of DNA In Vitro: The Polymerase Chain Reaction," Milestones in Biotechnology: Classic Papers on Genetic Engineering, Davies et al., eds., Buterworth-Heinemann, Stoneham, MA, pp. 17-27 (1992).
		·		Naumovski et al., "Outbreak of Ceftazidime Resistance Due to a Novel Extended-Spectrum β-Lactamase in Isolates from Cancer Patients," <u>Antimicrob. Agents Chemother.</u> , 36(9):1991-1996 (1992).
•.	-			Nordmann et al., "Characterization of a Novel Extended-Spectrum β-Lactamase from <i>Pseudomonas aeruginosa</i> ," <u>Antimicrob. Agents Chemother.</u> , <u>37</u> (5): 962-969 (1993).
				Nüesch-Inderbinen et al., "Detection of Genes Coding for Extended-Spectrum SHV Beta-Lactamases in Clinical Isolates by a Molecular Genetic Method, and Comparison with the E Test," <u>Eur. J. Clin. Microbiol. Infect. Dis.</u> , <u>15</u> :398-402 (1996)
				O'Callaghan et al., "Inhibition of β-Lactamase Decomposition of Cephaloridine and Cephalothin by Other Cephalosporins," <u>Antimicrob. Agents Chemother.</u> , 337-343 (1967).
				Philippon et al., "Minireview Extended-Spectrum β-Lactamases," <u>Antimicrob.</u> <u>Agents Chemother.</u> , <u>33</u> (8):1131-1136 (1989).
)	Piddock et al., "Prevalence and mechanism of resistance to 'third-generation' cephalosporins in clinically relevant isolates of Enterobacteriaceae from 43 hospitals in the UK, 1990-1991," <u>J. Antimicrob.Chemother.</u> , <u>39</u> :177-187 (1997).
			-	Pitout et al., "β-Lactamases Responsible for Resistance to Expanded-Spectrum Cephalosporins among <i>Klebsiella pneumoniae</i> , <i>Escherichia coli</i> and <i>Proteus mirabilis</i> Isolates Recovered in South Africa," <u>96th ASM General Meeting</u> , Poster and Abstract A-46, p.141 (May 1996).
		\bigvee		Pitout et al., "β-Lactamases Responsible for Resistance to Expanded-Spectrum Cephalosporins in <i>Klebsiella pneumoniae</i> , <i>Escherichia coli</i> , and <i>Proteus mirabilis</i> Isolates Recovered in South Africa," <u>Antimicrob. Agents Chemother.</u> , 42(6):1350-1354 (1998).

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Page 6 of 7

INFORMATION DISCLOSURE STATEMENT

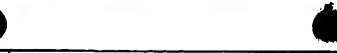
 Atty. Docket No.: 180.00030103
 Serial No.: 09/814,252

 Applicant(s): Hanson et al.
 Confirmation No.: 6198

 Filing Date: March 21, 2001
 Group: 1655 /634

O 15				
AUG 1 7	2007 (196 AD		Pitout et al., "Plasmid-Mediated Resistance to Expanded-Spectrum Cephalosporins among Enterobacter aerogenes Strains," Antimicrob. Agents Chemother., 42(3):596-600 (1998).
ENTR TRAD	EMARK			Prodinger et al., "Molecular Epidemiology of Klebsiella pneumoniae Producing SHV-5 β-Lactamase: Parallel Outbreaks Due to Multiple Plasmid Transfer," J. Clin. Microbio., 34(3):564-568 (1996).
				Resigner PCR from Research Genetics. Advertisment in Nucleic Acis Res., 22(15)
			/	Saiki et al., "Enzymatic Amplification of β-Globin Genomic Sequences and Restriction Site Analysis for Diagnosis of Sickle Cell Anemia," Science, 230, 1350-1354 (1985).
				Saiki et al., "Analysis of enzymatically amplified β-globin and HLA-DQα DNA with allele-specific oligonucleotide probes," Nature, 324:163-166 (1986).
				Sanchez et al., "The E-Test Applied to Susceptibility Tests of Gonococci, Multiply-Resistant Enterococci, and Enterobacteriaceae Producing Potent β-Lactamases," <u>Diagn. Microbiol. Infect. Dis.</u> , <u>15</u> :459-463 (1992).
·		·		Sanders et al., "New Service Notification," distributed by Center for Research in Anti-Infectives and Biotechnology, Creighton University School of Medicine (September 28, 1997)
				Sanders et al., "Characterization of β-Lactamases In Situ on Polyacrylamide Gels," <u>Antimicrob. Agents Chemother.</u> , 30(6):951-952 (1986).
				Sanders, Jr. et al., "Enterobacter spp.: Pathogens Poised To Flourish at the Turn of the Century," Clin. Microbiol. Rev., 10(2):220-241 (1997).
:				Sayeed et al., "Expression of Aeromonas caviae bla genes in Escherichia coli," <u>J.</u> Antimicrob. Chemother., 38:435-441 (1996).
·				Scharf et al., "Direct Cloning and Sequence Analysis of Enzymatically Amplified Genomic Sequences," <u>Science</u> , <u>233</u> , 1076-1078 (1986).
				Schmitz et al., "Specific information concerning taxonomy, pathogenicity and methicillin resistance of staphylococci obtained by a multiplex PCR," <u>J. Med. Microbiol.</u> , <u>46</u> :773-778 (1997).
		/		Sirot et al., "A Complex Mutant of TEM-1 β-Lactamase with Mutations Encountered in Both IRT-4 and Extended-Spectrum TEM-15, Produced by an Escherichia coli Clinical Isolate," Antimicrob. Agents Chemother., 41(6):1322-1325 (1997).
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EXAMINER	Tule	u	Date Considered	3	N/2003	>
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Page 7 of 7

INFORMATION DISCLOSURE STATEMENT

 Atty. Docket No.: 180.00030103
 Serial No.: 09/814,252

 Applicant(s): Hanson et al.
 Confirmation No.: 6198

 Filing Date: March 21, 2001
 Group: 1655 634

OIP	E			
AUG 1 7	2801			Sutcliffe, "Nucleotide sequence of the ampicillin resistance gene of Escherichia coli plasmid pBR322," Proc. Natl. Acad. Sci. USA, 75(8):3737-3741 (1978).
ENTE TRI	DEMAR			Tenover et al., "Development of PCR Assays to Detect Ampicillin Resistance Genes in Cerebrospinal Fluid Samples Containing Haemophilus influenzae," J. Clin. Microb., 32(11):2729-2737 (1994).
				Tenover et al., "SHEA Position Paper: How to Select and Interpret Molecular Strain Typing Methods for Epidemiological Studies of Bacterial Infections: A Review for Healthcare Epidemiologists," Infect. Control and Hosp. Epidemiol., 18(6):426-439 (1997).
				Thomson et al., "High-Level Resistance to Cefotaxime and Ceftazidime in Klebsiella pneumoniae Isolates from Cleveland, Ohio," Antimicrob. Agents Chemother., 35(5):1001-1003 (1991).
			\int	Thomson et al., "Detection of Extended-Spectrum β-Lactamases in Members of the Family <i>Enterobacteriaceae</i> : Comparison of the Double-Disk and Three-Dimensional Tests," <u>Antimicrob. Agents Chemother.</u> , 36(9):1877-1882 (1992).
			ſ	Tolmasky, "Sequencing and Expression of aadA, bla, and tnpR from the Multiresistance Transposon Tn1331," Plasmid, 24, 218-226 (1990).
				Towner, "Leading article: Detection of antibiotic resistance genes with DNA probes," <u>J. Antimicrob. Chemother.</u> , <u>30</u> :1-2 (1992).
			<i></i>	Vercauteren et al., "Comparison of Screening Methods for Detection of Extended-Spectrum β-Lactamases and Their Prevalence among Blood Isolates of Escherichia coli and Klebsiella spp. in a Belgian Teaching Hospital," J. Clin. Microb., 35(9):2191-2197 (1997).
				Walsh et al., "Sequence analysis of two chromosomally mediated inducible β-lactamases from <i>Aeromonas sobria</i> , strain 163a, one a class D penicillinase, the other an AmpC cephalosporinase," <u>J. Antimicrob. Chemother.</u> , <u>36</u> : 41-52 (1995).
	\	C		Zhou et al., "Emergence of Clinical Isolates of Escherichia coli Producing TEM-1 Derivatives or an OXA-1 β-Lactamase Conferring Resistance to β-Lactamase Inhibitors," Antimicrob. Agents Chemother., 38(5):1085-1089 (1994).

EXAMINER Date Considered 3/1/ws

INFORMATION DISCLOSURE TATEMENT

Atty. Docket No.: 180.0003 0103 Serial No.: 09/814,252 Applicant(s): Hanson et al. **Confirmation No.:** 6198 Group: 1655 /634

U.S. PATENT DOCUMENTS Subclass Filing Date If raminer **Document Number** Date Name Class Initial Appropriate NONE TECH CHNTER 1600/2900 FOREIGN PATENT DOCUMENTS **Document Number** Class Subclass Date Country Translation Yes No WO 91/08305 06/1991 **PCT** OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.) Leegaard et al., "Antibiotic resistance mechanisms in Salmonella species causing bacteraemia in Malawi and Kenya", <u>ΛΡΜΙS</u>, <u>104</u>:302-306 (1996). Siu et al., "Correlation of in vitro susceptibility testing results for amoxicillin-clavulanate and ampicillin-sulbactam using a panel of beta-lactamase-producing Enterobacteriaceae", APMIS, <u>106</u>:917-920 (1998). Speldooren et al., "Discriminatory detection of inhibitor-resistant beta-lactamases in Escherichia coli by single-strand conformation polymophism-PCR", Antimicrobial Agents and Chemotherapy, <u>42</u>:879-884 (1998). Vahaboglu et al., "Practical approach for detection and identification of OXA-10-derived ceftazidime-hydrolyzing extended spectrum beta-lactamses", J. Clin. Microbiology, 36:827-829 (1998).

Filing Date: March 21, 2001

EXAMINER Date Considered 3/1/203
